REMARKS

Claims 1-11 are pending in the present application.

At the outset, Applicants wish to thank Examiner Moore for the indication that the elected portions of Claims 1-4 and 9 that are drawn to the specific aminopeptidase isolated from *A. nidulans* are free from the art of record. Reconsideration of the remaining rejections is respectfully requested in view of the amendments and remarks set forth herein.

The rejections of Claims 1-3 and 5-9 under 35 U.S.C. §112, first paragraph (enablement and written description), are obviated in part by amendment and traversed in part.

The Office has alleged that the specification fails to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (page 5 of the Office Action mailed September 29, 2005). It appears that this ground of rejection is based on: (a) the breadth of permissible homologs to SEQ ID NO: 5, and (b) the lack of a definition for the "stringent" conditions.

First, with respect to (b), Applicants have amended Claim 3 to specify the conditions that qualify as "stringent." The conditions and applicability of the now recited stringent conditions appears on page 6, line 27 to page 7, line 8 of the specification. Inspection of the database of granted patents indicates that these conditions are routinely recognized by the Office as meeting the written description requirements of 35 U.S.C §112, first paragraph.

With respect to (a), Applicants have amended the claims based on the specification at page 6, lines 1-8 to define the scope homologs and the type of mutations. In addition, the specification and the claims clearly specify that in order for a sequence to fall within the

scope of the claimed invention it would have to possess the specifically recited activity requirements. The specification, at pages 13-24, provides painstaking details on how the artisan would clone, express, and purify candidate proteins, as well as how to assess the activity of the candidate proteins to determine whether they fall within the scope of the claimed invention.

MPEP § 2163.02:

> An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989).

Applicants submit that the specification provides an adequate description to allow the skilled artisan to recognize what has been invented and what is claimed is adequately described in the specification within the meaning of 35 U.S.C. § 112, first paragraph. Accordingly, the written description rejection should be withdrawn.

The Office has also taken the position that the claimed invention is not supported by an enabling disclosure (page 6 of the Office Action mailed September 29, 2005). In particular, the Office has taken the position that the specification fails to enable the breadth of homologs presented in the original claims. Applicants respectfully disagree.

Nonetheless, the claims have been amended to specifically define the number of amino acid positions that may be substituted, deleted, or added as being up to 170. Applicants submit that the specification fully enables this scope.

MPEP §2164.04 states:

> A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth

> of the statements contained therein which must be relied on for enabling support.

At pages 13-24, Applicants provide a detailed explanation of how the skilled artisan may clone, express, and characterize the polynucleotides and proteins that fall within the scope of the present invention. Moreover, in the Examples Applicants provide a detailed example of how to assess the activity of candidate proteins to determine whether they meet the limitations of the claimed invention.

MPEP § 2164.01 states:

> The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.

Applicants submit that determining what sequences fall within or without the scope of the present claims would be readily apparent to the skilled artisan with the present application in hand. As stated above, at pages 13-24, Applicants provide a detailed example of how the skilled artisan may clone, express, and characterize any sequence variant to assess its standing with respect to the claimed invention. The Examiner has provided a rather nice account of some of the difficulties associated with predicting activity from sequence and structure. However, this discourse further underscores the fact that the activity recited in the present claims provides sufficient direction with respect to the scope of these claims, as well as the importance of the disclosure of the present invention to provide the skilled artisan with express guidance to assess the recited activity.

In fact, MPEP §2164.06 states:

> ... quantity of experimentation needed to be performed by one skilled in the art is only one factor involved in determining whether "undue experimentation" is required to make and use the invention. "[A]n extended period of experimentation may not be undue if the skilled artisan is given sufficient direction or guidance." In re Colianni, 561 F.2d 220, 224, 195 USPQ 150, 153

> (CCPA 1977). " 'The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.

Applicants submit that, with the present specification in hand, determination of polynucleotide sequences that fall within the scope of the present invention would require nothing more than routine experimentation to determine sequence homology and protein activity. As such, Applicants submit that the claims of the present application are fully enabled within the context of 35 U.S.C. §112, first paragraph.

Based on the foregoing, Applicants submit that the present claims are fully described and enabled by the specification and the common knowledge available in the art and as such withdrawal of these grounds of rejection is requested.

The rejections of: (a) Claims 1-3 and 5 under 35 U.S.C. §102(b) over Chang et al; and (b) Claims 1-3 and 5-8 under 35 U.S.C. §102(b) over Smith et al, are obviated by amendment.

Chang et al and Smith et al are cited as disclosing a sequence from *S. cerevisiae* having 42% identity to SEQ ID NO:5 and a sequence having 42.4 % identity to SEQ ID NO: 4. Specifically, the Examiner cites the foregoing references as disclosing a leucine aminopeptidase that shares only 205 common amino acids with SEQ ID NO: 5. In the amendment herein, Applicants have defined the scope of homologs as those sharing at least 340 amino acids (i.e., up to 170 substituted, added, or deleted amino acids). As such, neither Chang et al nor Smith et al anticipate the claimed invention.

In view of the foregoing, Applicants request withdrawal of these grounds of rejection.

The rejection of Claims 1-3 and 5-9 under 35 U.S.C. §112, second paragraph, is obviated by amendment.

Applicants have amended the claims to specifically address the various criticisms raised by the Examiner.

Applicants request withdrawal of this ground of objection.

The rejection of Claims 1-9 under 35 U.S.C. §101 is believed to be obviated by the amendments herein. Applicants have amended the claims to ensure that the claimed invention is distinguished from products of nature (i.e., require the 'hand of man'). As such, Applicants request that the Examiner withdraw this ground of rejection.

The objections to Claims 3 and 6-9 are believed to be obviated by the amendments herein. Applicants have amended the claims to specifically address the various criticisms raised by the Examiner. In view of the amendments to the claims, Applicants request withdrawal of this ground of objection.

The objection to the specification for containing an embedded hyperlink is obviated by amendment. Applicants have deleted the hyperlink that originally appeared on page 13 of the specification. Withdrawal of this ground of objection is requested.

Applicants submit that the present application is in condition for allowance. Early notification to this effect is respectfully requested.

Respectfully submitted,

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